



Food and Drug Administration
Rockville MD 20857

#16

Re: Tisseel VH Kit
Docket No.: 98E-0791

NOV - 4 1998

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, DC 20231

ASSISTANT SECRETARY
AND COMMISSIONER
38 NOV 12 AM 11:09
U.S. PATENT
AND
TRADEMARK OFFICE

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 4,362,567, filed by Immuno Aktiengesellschaft fur chemisch-medizinische Produkte, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Tisseel VH Kit, the human biological product claimed by the patent.

The total length of the regulatory review period for Tisseel VH Kit is 5,065 days. Of this time, 1,203 days occurred during the testing phase and 3,862 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this biologic product became effective: June 20, 1984.

FDA has verified the applicant's claim that the date the Investigational New Drug application became effective was on June 20, 1984.

2. The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act: October 5, 1987.

FDA has verified the applicant's claim that the product license application (PLA) for Tisseel VH Kit (PLA 87-0509) was initially submitted on October 5, 1987.

3. The date the application was approved: May 1, 1998.

FDA has verified the applicant's claim that PLA 87-0509 was approved on May 1, 1998.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

A handwritten signature in cursive script that reads "Thomas J. McGinnis".

Thomas J. McGinnis, R.Ph.
Deputy Associate Commissioner
for Health Affairs

cc: John L. Isacson
Foley & Lardner
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